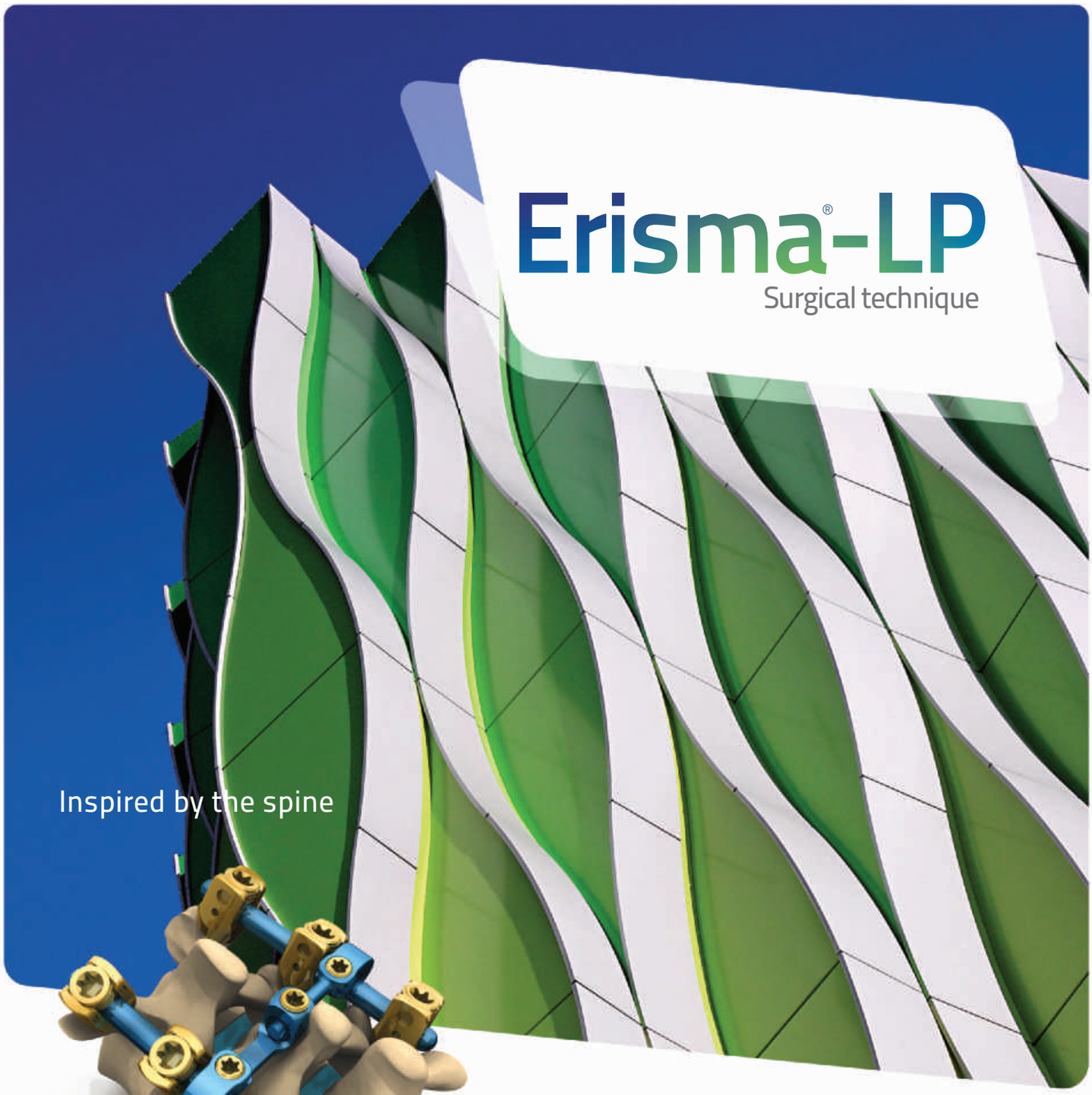
Erisma®-LP

Surgical technique



Inspired for the spine

FUSION TECHNOLOGIES

CLARIANCE
innovation for spine surgery

Contents

Introduction

Designed by a team with extensive expertise in the development of spinal instrumentation, Erisma–LP is the result of optimized development based on an analysis of existing technologies.

The Erisma–LP spinal instrumentation is a pedicle screw based fixation. The design team focused on creating a top loading system that incorporates reduced implant volume and ergonomically designed instrumentation. Erisma–LP was developed to meet the spine surgeon's needs for reliability, security and ease of use during day-to-day surgical practice. Erisma–LP is a comprehensive system of implants and instruments designed to address pathologies of the spine in the thoraco-lumbar region. Composed of polyaxial screws, monoaxial screws, crosslinks, rods and set screws, Erisma–LP integrates a wide selection of sizes and diameters, allowing the surgeon to perform posterior fixation of the spine for various pathologies.

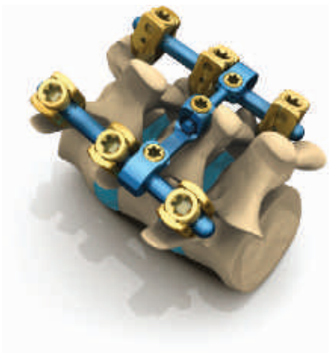
Indications:

- Disc Degenerative disease
- Spondylolisthesis
- Spinal stenosis
- Lumbar deformities
- Trauma
- Tumor
- Pseudarthrosis
- Failed previous fusion

Features & benefits

Optimized volume and profile

Limited interference with anatomical features



Tapered thread

Enhanced strength under bending moments

Self-tapping blunt tip

Easy, smooth and non-aggressive screw insertion

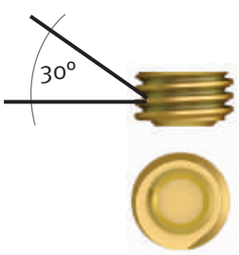
Color-coded screws and taps

Quick screw selection

Buttress thread

No splaying of the screw head

Optimized performance of the screw/rod connection

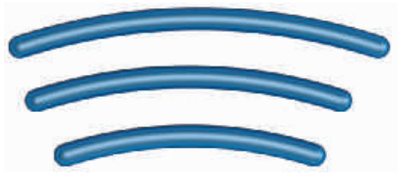


Optimized thread entry

Prevents cross-threading

Short pre-bent rods

Quick rod preparation



Straight rods with guiding line

Facilitate bending of the rod within one plane

Facilitate rod positioning

Fully adjustable crosslink

Easy implantation in all configurations

User-friendly

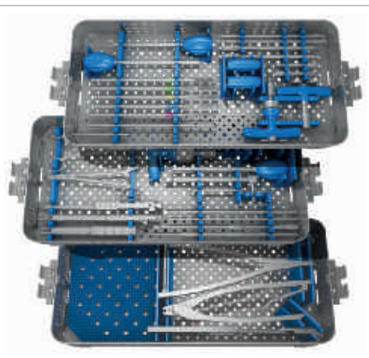
Precise, quick and efficient maneuvers

Quick connect and modular handles

Adaptability to the surgeon's habits

Ergonomic design

Complete instrumentation, compact instrument set



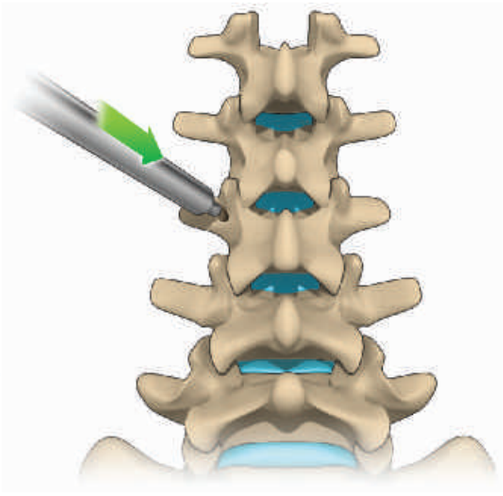
Surgical Technique

Following all necessary safety protocols, the patient is positioned on the operating table in the prone position. The surgical approach is performed according to the known and validated techniques routinely used by surgeons.

Pedicle preparation 1

99702000 SQUARE AWL

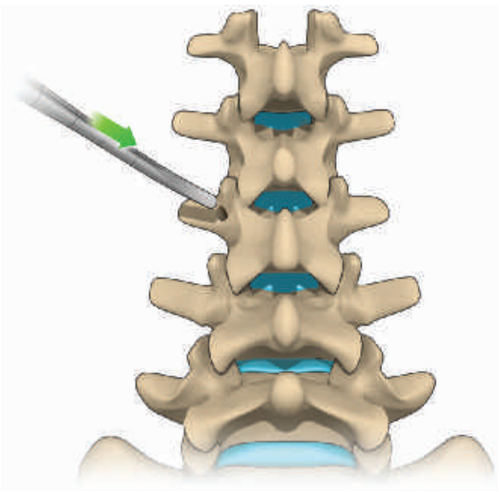
After adequate exposure, the appropriate pedicle entry point is located and the entrance to the pedicle canal is perforated using the square awl.



Pedicle drilling and screw selection

2

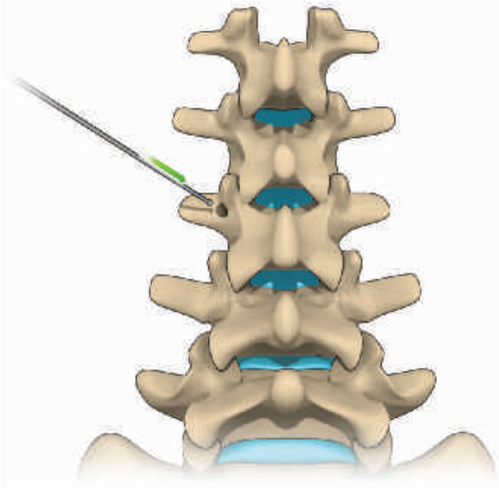
A pathway in the intrapedicular cancellous bone is then opened up using the pedicle probe at the appropriate angle and depth. The pedicle probe is graduated with 10mm intervals to determine the depth measurement, as well as to determine the proper screw length.



99731000 PEDICLE PROBE

99730000 PEDICLE SOUNDER

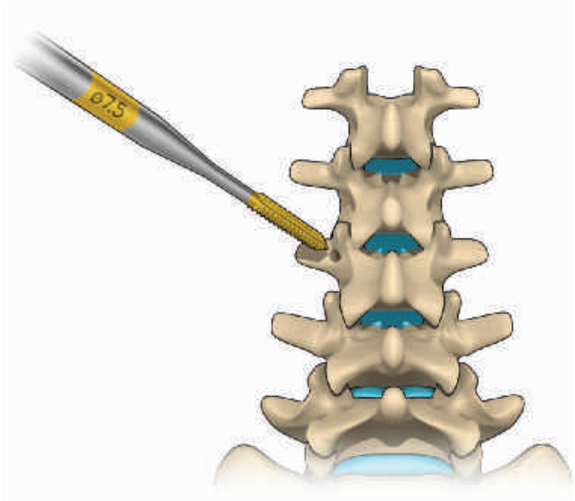
The integrity of the pedicular hole's walls is then checked with the pedicle sounder.



Tapping

3

The Erisma–LP screws are self-tapping and do not require tapping. For the surgeon's convenience, optional tapping can be performed using the taps provided in all diameters. The screw diameter is determined by the color-code indicated on the tap.



997010** TAP

18710002
HOLDING SCREWDRIVER

HANDLES

Pedicle screw insertion

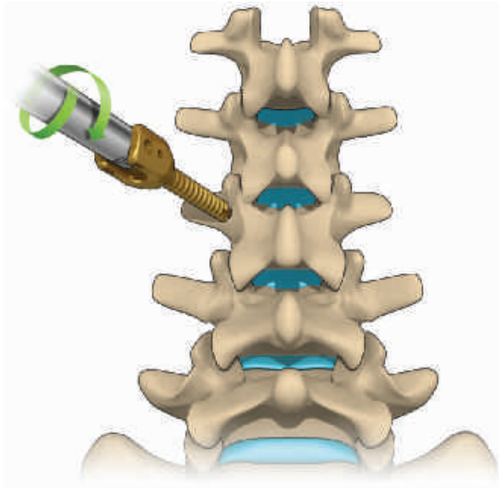
4

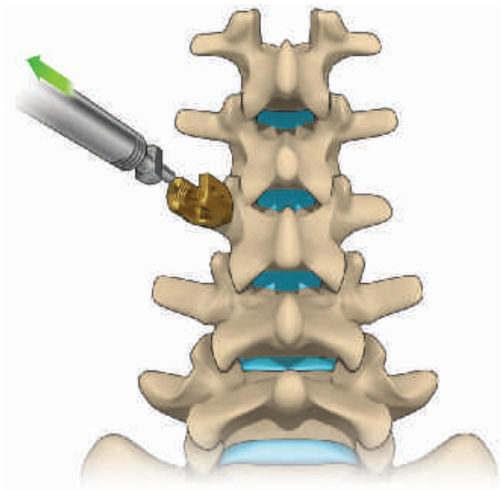
The appropriate screw diameter and length are determined.

The proper screw length may be checked using the screw gauge placed on the instrument tray.

To implant the screw, fully engage the tip of the holding screwdriver in the head of the screw ① and turn the locking knob clockwise ②. Then, make sure that the screw is straight and secured ③.

The screw is inserted in the pedicle hole and the holding screwdriver is disengaged by turning the locking knob counterclockwise. Repeat for each screw.

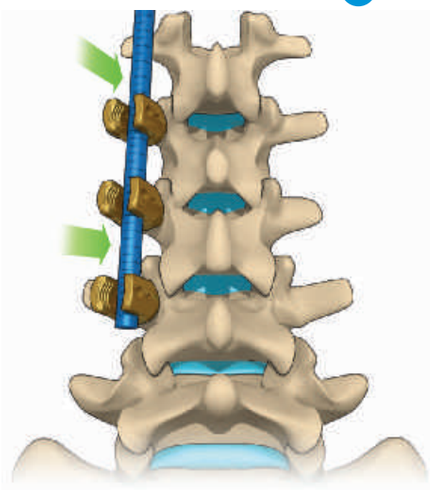




Rod preparation

5

Once the screws have been inserted and their positions have been verified by X-ray, the appropriate rod length is selected using the rod template. If necessary, bend the rod using the French bender to set the appropriate spinal contours.



99733*** ROD TEMPLATE

99750001 FRENCH BENDER

99715003
NARROW NOSE ROD HOLDER

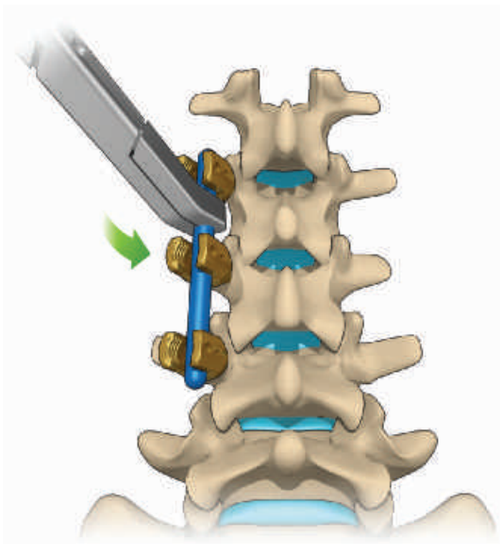
Rod insertion

6

The rod is inserted in the screw heads using the angled rod holding forceps. The Erisma–LP system offers two options for linking the rod to the screw heads:

Rod Pusher

When the rod is slightly above the screw head, the rod pusher may be used to push the rod into position.



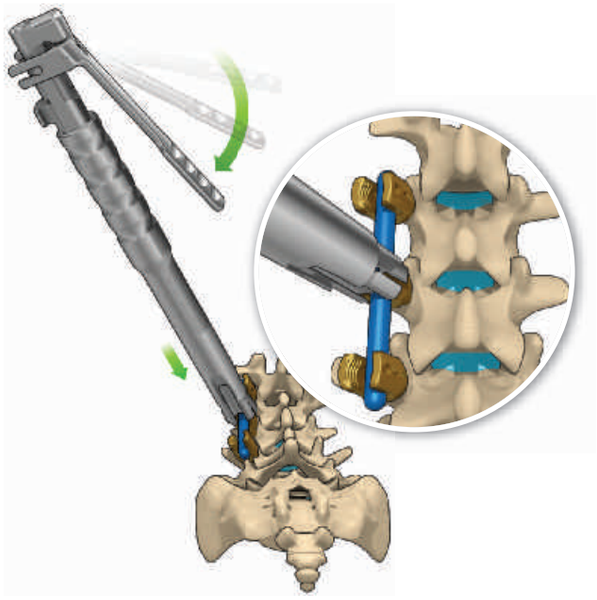
99715002
ANGLED ROD HOLDING FORCEPS

99743000 ROD PUSHER

18742002 PERSUADER

Persuader

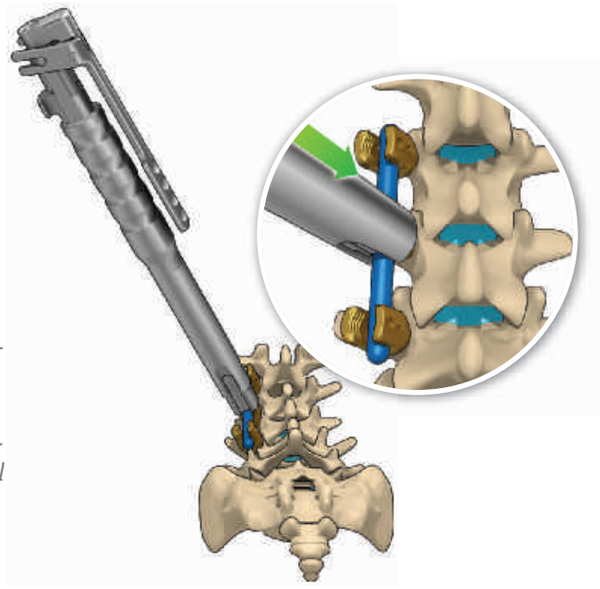
The persuader is used if additional force is needed to bring the rod to the implant. The persuader is connected to the head of the screw. The trigger is then pressed and the tube slid down.



Once the lever is pushed down, the rod is fully seated in the implant. When the introduction lever is tipped down, the persuader stays in position.

The lever can be pushed down only when the persuader is well-positioned on the implant and the tube slid down.

When finished, press the trigger again, slide the tube up and pull the lever up. The persuader can be removed and is ready to use again.



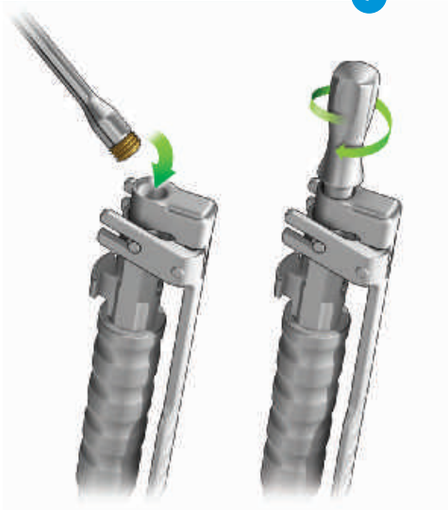
01714001 SET SCREW HOLDER

Set screw positioning

7

The set screws are fitted on the tip of the set screw holder and sequentially threaded on the implant. Only a few threads are necessary to secure the rod in the implants. Repeat for each set screw.

It is recommended to use the persuader to guarantee that the rod is perfectly in position and therefore, avoid possible cross-threading.



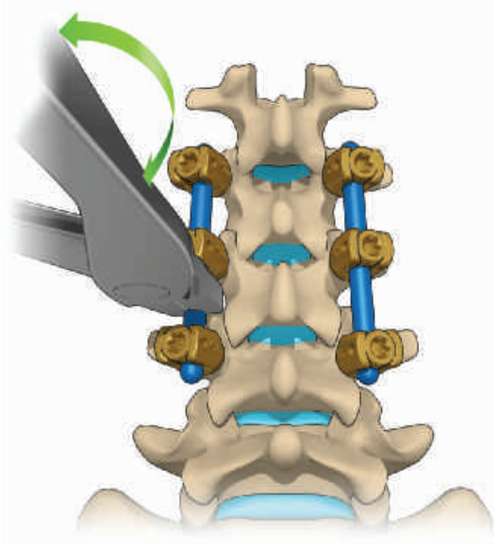
Correction maneuvers

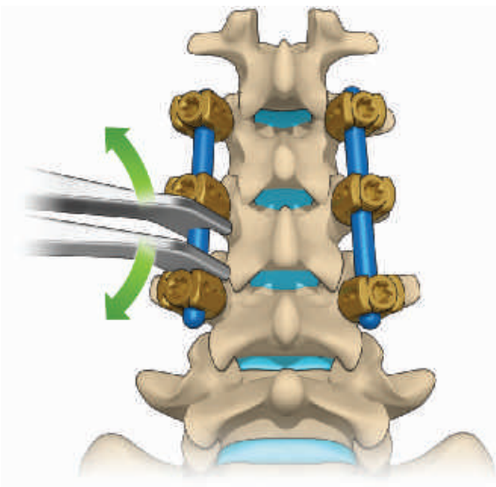
8

Before final tightening of the construct, rod rotation, compression or distraction may be achieved.

Rod rotation

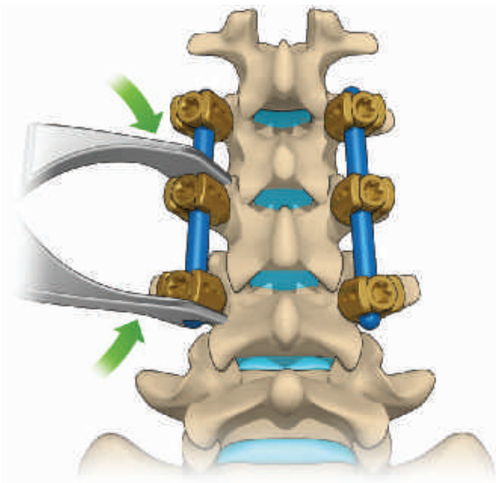
To achieve the final rod positionning, the rod can be turned using the narrow nose rod holder.





Distraction and compression

Segmental distraction or compression may be carried out using the compressor or the distractor.



99715003
NARROW NOSE ROD HOLDER

99741001 DISTRACTOR

99740001 COMPRESSOR

01721003 COUNTER TORQUE

99781200
TORQUE LIMITED T HANDLE

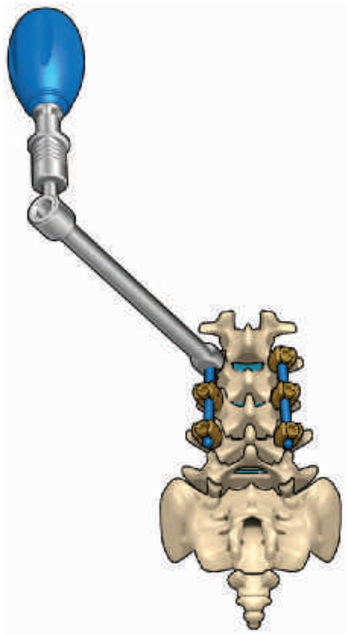
01720003
TIGHTENING WRENCH T30

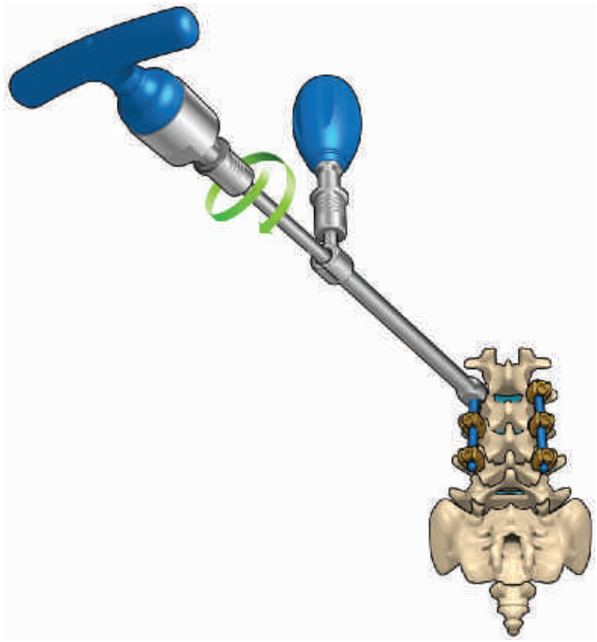
18733001 CROSSLINK TEMPLATE

Final tightening

9

The set screw is tightened using the tightening wrench T30 attached to the torque limited T-handle. The counter torque is positioned over the screw head and the wrench is inserted through the tube of the counter-torque. Tighten until the torque limited T-handle triggers once. Repeat for each screw.

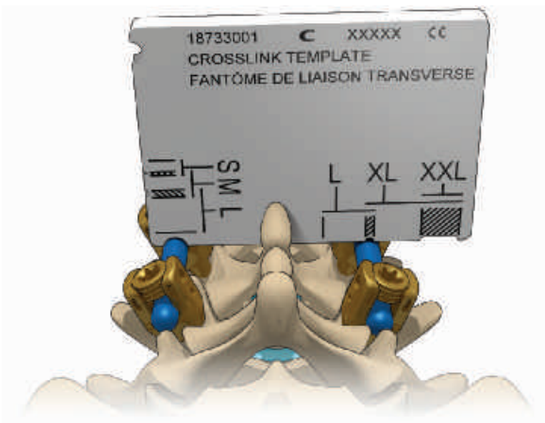




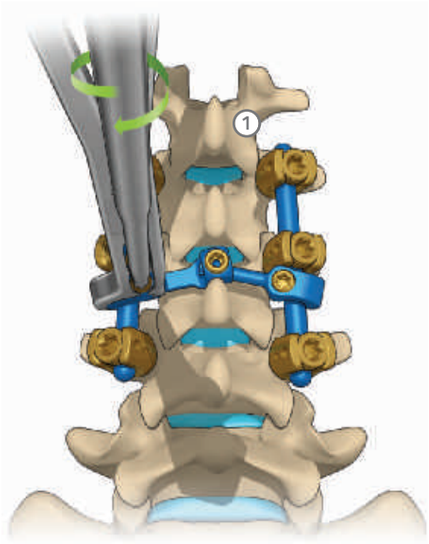
Crosslink placement

10

To complete the construct, a crosslink may be added to provide increased stability. The appropriate size of the crosslink (S, M, L, XL, XXL) is determined using the crosslink template.

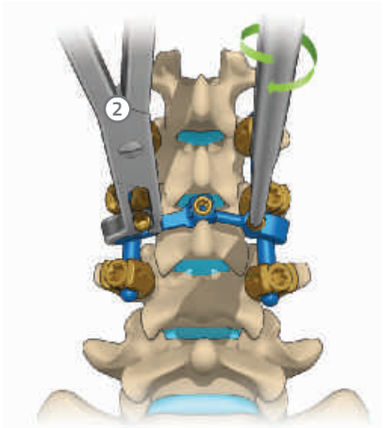


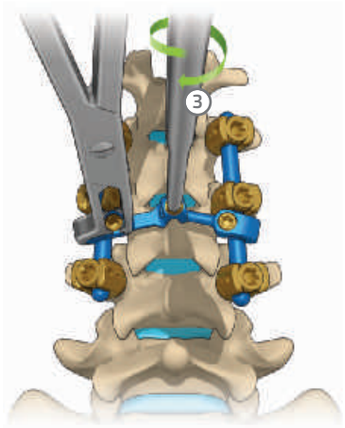
Once the crosslink size is determined and its unlocked position is checked, the crosslink holder is used to position the crosslink. The first transverse connector is positioned and its set screw is tightened using the tightening wrench ①. The operation is repeated for the second connector ②. When lateral set screws are secured, the center set screw is tightened ③.

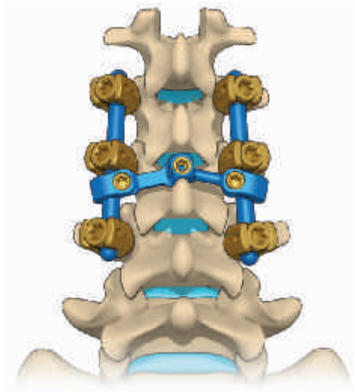


18713001 CROSSLINK HOLDER

01720001
TIGHTENING WRENCH T20







Removal

11

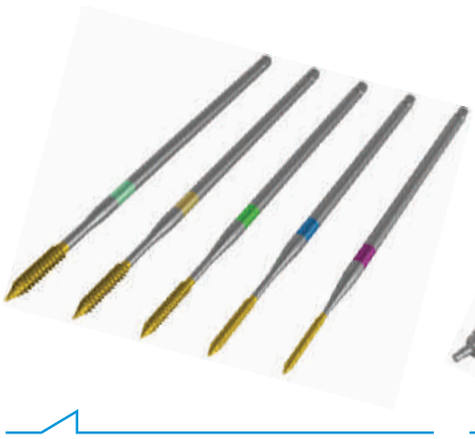
The set screws can be removed using the counter torque and the tightening wrench to turn the set screws counterclockwise. When the set screws are removed, the rod can be easily extracted using the angled rod holding forceps. The holding screwdriver is used to remove the screws.

Product catalog

SQUARE AWL 99702000

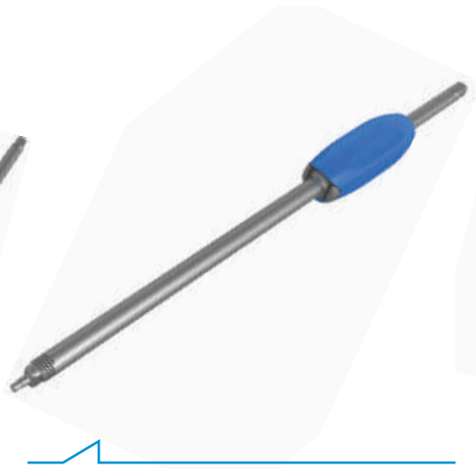
PEDICLE SOUNDER 99730000

PEDICLE PROBE 99731000



TAP

ø4.5mm	99701045
ø5.5mm	99701055
ø6.5mm	99701065
ø7.5mm	99701075
ø8.5mm	99701085



HOLDING SCREWDRIVER 18710002

FIXED PALM HANDLE	99780000
NON RATCHETING T-HANDLE	99781000
RATCHETING HANDLE	99781100
TORQUE LIMITED T-HANDLE	99781200

ANGLED ROD HOLDING FORCEPS 99715002

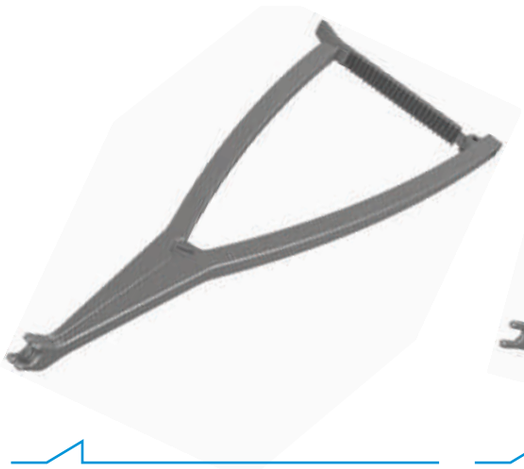
FRENCH BENDER 99750001

NARROW NOSE ROD HOLDER 99715003

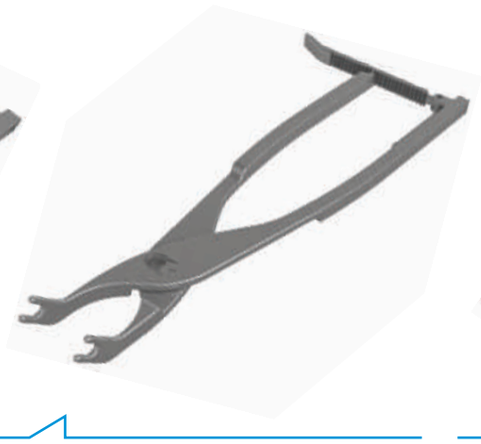
ROD PUSHER 99743000

PERSUADER 18742002

SET SCREW HOLDER 01714001



DISTRACTOR 99741001



COMPRESSOR 99740001

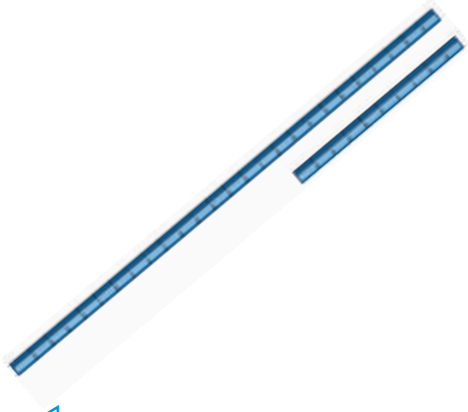
COUNTER TORQUE 01721003

TIGHTENING WRENCH T30 01720003
TIGHTENING WRENCH T20 01720001

CROSSLINK TEMPLATE 18733001

Product catalog

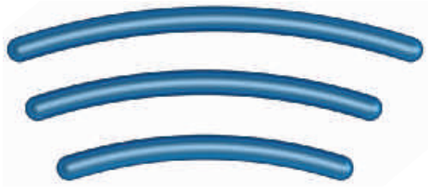
CROSSLINK HOLDER 18713001



ROD TEMPLATE		
	length 100 mm	99733100
	length 250 mm	99733250

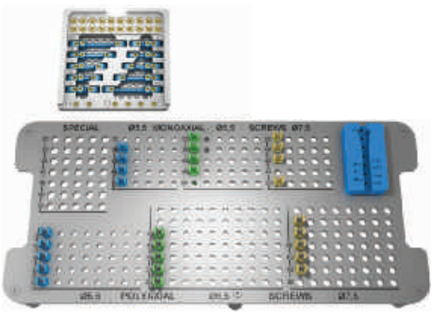
CROSSLINK		
	S (27-31 mm)	18442731
	M (30-37 mm)	18443037
	L (35-47 mm)	18443547
	XL (45-67 mm)	18444567
	XXL (58-93 mm)	18445893

SET SCREW 18620009

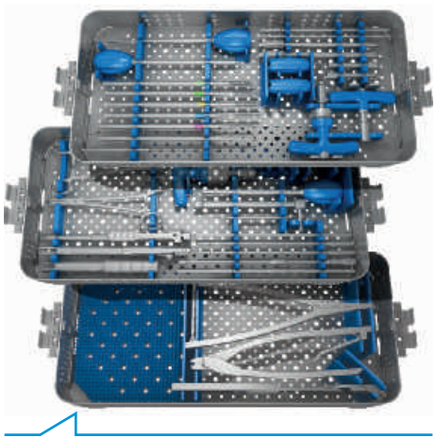


BENT ROD		
	length 30 mm	18415503
	length 40 mm	18415504
	length 50 mm	18415505
	length 60 mm	18415506
	length 70 mm	18415507
	length 80 mm	18415508
	length 90 mm	18415509
	length 100 mm	18415510

ROD		
	length 120 mm	18455512
	length 140 mm	18455514
	length 160 mm	18455516
	length 180 mm	18455518
	length 200 mm	18455520
	length 220 mm	18455522
	length 240 mm	18455524



IMPLANTS TRAY 18790001



INSTRUMENTS TRAY 18790002

MONOAXIAL SCREW

Length (mm)	ø4.5	ø5.5	ø6.5	ø7.5	ø8.5
25	*	*	—	—	—
30	*	18015530	18016530	—	—
35	*	18015535	18016535	18017535	*
40	*	18015540	18016540	18017540	*
45	—	18015545	18016545	18017545	*
50	—	*	18016550	18017550	*

* Available upon request

POLYAXIAL SCREW

Length (mm)	ø4.5	ø5.5	ø6.5	ø7.5	ø8.5
25	*	*	—	—	—
30	*	18045530	18046530	—	—
35	*	18045535	18046535	18037535	*
40	*	18045540	18046540	18037540	*
45	—	18045545	18046545	18037545	*
50	—	*	18046550	18037550	*

* Available upon request

FR Notice d'instructions

L'instrumentation Erisma–LP est destinée au traitement chirurgical des pathologies rachidiennes. Ce traitement consiste à fusionner un segment de deux ou plusieurs vertèbres avec ou sans geste chirurgical endocanalaire associé, pour lui donner une stabilité. Pour optimiser le résultat, un diagnostic préopératoire détaillé, une technique chirurgicale méticuleuse ainsi que des soins postopératoires adaptés sont indispensables. Il est important que le patient et le chirurgien soient pleinement conscients des risques et complications inhérents à ce type de chirurgie. Cette technique exige que le chirurgien soit expérimenté dans le placement des vis pédiculaires dans des vertèbres. Nous conseillons au chirurgien de suivre une formation auprès d'un chirurgien déjà expérimenté avant de démarrer l'utilisation de cette technique.

1 | DESCRIPTION

L'instrumentation Erisma–LP est composée de tiges fixées sur la colonne vertébrale à l'aide de vis pédiculaires. En outre, elle comporte une liaison transverse qui relie deux tiges entre elles. Les implants de l'instrumentation Erisma–LP sont réalisés en alliage de titane selon la norme ISO 5832-3 ou ASTM F136 rappelé par le symbole Ⓣ. Il est impératif d'utiliser les implants Erisma–LP avec le matériel ancillaire conçu à cet effet. Pour obtenir un descriptif plus détaillé du matériel, il est nécessaire de se référer à la documentation technique. Le matériel Erisma–LP doit être assemblé avec des éléments neufs définis comme étant compatibles entre eux.

2 | INDICATIONS

Les critères et principes généraux pour poser les indications en matière de chirurgie rachidienne s'appliquent.
- Pathologies dégénératives
- Déformation rachidienne
- Traumatologie
- Pathologie tumorale

3 | CONTRE INDICATIONS

- Grossesse
- Infection
- Allergie reconnue au matériau

4 | EFFETS SECONDAIRES, COMPLICATIONS POSSIBLES

- Pseudarthrose
- Démontage ou rupture d'implant
- Infection, Allergie au matériau

5 | PRECAUTIONS D'EMPLOI

Ne jamais réutiliser un implant même en parfait état. Tout implant ayant été utilisé, déformé, tordu, courbé, implanté puis retiré, même s'il apparaît intact doit être éliminé. Ceci est rappelé sur l'étiquette par le symbole Ⓢ. Utiliser systématiquement des implants neufs. Ne pas mélanger des matériaux différents.

- **Préopératoire :** Le chirurgien doit maîtriser parfaitement tous les aspects de la technique chirurgicale, connaître les indications et contre-indications. Le chirurgien doit vérifier qu'aucun facteur d'origine biologique, biomécanique ou autre ne viendra affecter le bon déroulement de l'intervention et de ses suites. Un éventail adéquat des tailles doit être disponible lors de l'intervention.

- **Per-opératoire :** La sélection correcte du type et de la taille des implants adaptés au patient, ainsi que son positionnement sont extrêmement importants.

- **Postopératoire :** Les patients doivent être informés des précautions à prendre dans leur vie quotidienne afin de garantir la durée de vie maximale des implants. Il est recommandé d'effectuer un contrôle postopératoire régulier qui permet de mettre en évidence des signes précoces de faillite du matériel. Les implants peuvent être retirés après la consolidation osseuse. La dégradation du dispositif après consolidation osseuse ne peut être considérée comme un dysfonctionnement ou une altération des caractéristiques du matériel. Un programme de rééducation adapté doit être établi et mis en œuvre.

6 | MANIPULATION / STOCKAGE

La manipulation du matériel Erisma–LP doit être effectuée aussi peu souvent que possible et avec précautions. Le stockage des implants Erisma–LP (dans leur conditionnement d'origine) doit être réalisé avec soin dans un environnement propre et sec. Ne pas exposer les implants Erisma–LP à des rayonnements ou à des températures extrêmes. Le non-respect de ces prescriptions peut provoquer une baisse des caractéristiques mécaniques pouvant conduire dans certains cas, à leur rupture. Les instruments chirurgicaux spécifiques à l'instrumentation Erisma–LP devront être vérifiés sur le plan fonctionnel avant toute intervention.

7 | PRÉ-TRAITEMENT / NETTOYAGE / STERILISATION :

Les opérations de nettoyage, décontamination et stérilisation sont impératives pour les implants et les instruments avant et après utilisation. Les implants et les instruments en sachet doivent être sortis de leur emballage d'origine pour les opérations de prétraitement, de nettoyage et de stérilisation qui seront mises en œuvre suivant les recommandations de bonnes pratiques en vigueur. Les implants doivent être stérilisés avant emploi. Il est recommandé de stériliser les implants dans un autoclave à vapeur selon la méthode employée dans les hôpitaux et les cliniques (valeurs recommandées ci-dessous).

Méthode de stérilisation :	Autoclave
Cycle	Prion
Température	134°C
Durée d'exposition	18 min (minimum)

Cependant nous conseillons aux utilisateurs qui ne suivent pas la méthode recommandée de valider leur méthode en faisant appel à des techniques de laboratoire appropriées.

EN Instructions for use

The Erisma–LP instrumentation is designed for the surgical treatment of spinal pathologies. The treatment consists of the fusion of two or several vertebrae in order to restore spinal stability, with or without any other endocanalar concomitant surgical procedure. For optimal results, a detailed preoperative evaluation, a meticulous surgical technique and adequate post-operative care are mandatory. It is important that both the patient and surgeon are fully aware of the risks and possible complications associated with this type of surgery. This technique requires that the surgeon be experienced in the placement of the pedicle screws in vertebrae. Before attempting this technique, surgeons are advised to attend a training course with a surgeon already experienced with the use of the device.

1 | DESCRIPTION

The Erisma–LP system is composed of rods fixed on the spine with pedicle screws. Moreover, this instrumentation includes transverse link which connects two rods altogether. The implants used in the Erisma–LP system are made of titanium alloy ISO 5832-3 or ASTM F136 as indicated by the symbol Ⓣ. It is essential to insert implants with instrumentation specifically designed for this purpose. For more description of the instrumentation it is necessary to read the technical documentation associated to the Erisma–LP product. The Erisma–LP implants must be assembled with new Erisma–LP components defined as being compatible with one another.

2 | INDICATIONS

General criteria and principles related to instrumented spinal surgery are applied here :
- Degenerative pathologies
- Spinal deformity
- Traumatology
- Tumor pathology

3 | CONTRA-INDICATIONS

- Pregnancy
- Infection
- Recognized allergies to titanium or titanium alloys

4 | SECONDARY AND POSSIBLE SIDE EFFECTS

- Pseudarthrosis
- Implant disassembly or implant failure
- Infection
- Allergy to materials used

5 | CAUTIONS OF USE

Never reuse an implant, even in perfect state. Any implant which has been used, twisted, bent, implanted and then removed, even if appears intact, must be discarded. Use new implants routinely. This is indicated on the labeling of the implant package by the next symbol Ⓢ. Do not mix dissimilar materials.

- **Preoperative :** The surgeon must be fully conversant with all aspects of the surgical technique and know the indications and contra-indications of this type of implant. The surgeon must have acquainted himself before the operation with the specific technique for insertion of the product which is available from the manufacturer. As part of the pre-operative examination, the surgeon must check that no biological, biomechanical or other factors will affect the correct conduct of the operation and the post-operative period. An appropriate range of sizes must be available at the time of the operation.

- **Intraoperative :** The correct selection of the type of size of implant appropriate to the patient and the positioning of the implant are extremely important.

- **Postoperative :** Patients must be informed of the precautions to be taken in their everyday life to guarantee a maximum implant service life. It is recommended that a regular postoperative follow-up be undertaken to detect early signs of failure of the implants and to consider the action to be taken. Deterioration of the device after bone consolidation cannot be considered to constitute a dysfunction or degradation in the characteristics of the implant. The implant can be removed after the consolidation of the bone graft. A suitable rehabilitation program must be designed and implemented.

6 | HANDLING AND STORAGE

The handling of the Erisma–LP material must be done as seldom as possible and always with the utmost care. The Erisma–LP implants (in their original packaging) must be stored with care in a clean and dry place. Do not expose the Erisma–LP implants to radiations or extreme temperatures. Should these requirements not be followed, reduced mechanical properties may occur which could lead to implant failure in some cases. Proper function of the surgical instruments specific to the Erisma–LP instrumentation should be verified prior to every surgical procedure.

7 | CLEANING / DECONTAMINATION / STERILISATION

The operations of cleaning, decontamination and sterilization must be realized for the implants and the instruments before and after use. All packaging must be removed before the operations of pre treatment, cleaning and sterilization which will be implemented according to the recommendations good practices in force. The implants must be sterilized before use. It is advisable to sterilize the implants in a steam autoclave according to the method used in hospitals and clinics (recommended values below).

Sterilization method	Autoclave
Cycle	Porous load (prion)
Temperature	134°C
Exposure time	18 Min (Minimum)

However we advise the users not following the recommended method to validate their methods by means of appropriate laboratory technique.

ES Manual de instrucciones

La instrumentación Erisma–LP está destinada al tratamiento quirúrgico de las patologías raquídeas. Este tratamiento consiste en fusionar un segmento de dos o varias vértebras con o sin actuación quirúrgica endocanalar asociada, para darle estabilidad. Para optimizar el resultado, son indispensables un diagnóstico preoperatorio detallado, una técnica quirúrgica meticulosa y cuidados postoperatorios adaptados. Es importante que el paciente y el cirujano sean plenamente conscientes de los riesgos y complicaciones inherentes a este tipo de cirugía. Esta técnica exige que el cirujano tenga experiencia en la colocación de los tornillos pediculares en vértebras. Recomendamos que, antes de utilizarla, el cirujano siga una formación con un cirujano experimentado.

1 | DESCRIPCIÓN

La instrumentación Erisma–LP está compuesta por barras fijadas en la columna vertebral mediante tornillos pediculares. Además, incluye una conexión transversal que une las dos barras entre ellas. Los implantes de la instrumentación Erisma–LP son en aleación de titanio según la norma ISO 5832-3, ASTM F136 señalada con el símbolo Ⓣ. Es imperativo utilizar los implantes Erisma–LP con los instrumentos diseñados a tal efecto. Para obtener una descripción más detallada del material, referirse a la documentación técnica. El material Erisma–LP debe ensamblarse con elementos nuevos definidos como compatibles entre ellos.

2 | INDICACIONES

Se aplican los criterios y principios generales para las indicaciones en materia de cirugía raquídea.
- Patología degenerativa
- Deformación raquídea
- Traumatología
- Patología tumoral

3 | CONTRAINDICACIONES
- Embarazo
- Infección
- Alergia reconocida al titanio y aleaciones de Titanio

4 | EFECTOS SECUNDARIOS, COMPLICACIONES POSIBLES
- Pseudarthrosis
- Desmontaje o ruptura del implante
- Infección
- Alergia al material

5 | PRECAUCIONES DE EMPLEO

No reutilizar nunca un implante, incluso si está en perfecto estado. Todo implante que haya sido utilizado, deformado, torcido, curvado, implantado y después retirado, incluso si parece intacto, debe ser desechado. Està recordado en la etiqueta con el símbolo Ⓢ. No mezclar materiales diferentes. Utilizar sistemáticamente implantes nuevos.

- **Preoperatorio :** El cirujano debe dominar perfectamente todos los aspectos de la técnica quirúrgica, y conocer las indicaciones y contraindicaciones. También debe verificar que ningún factor de origen biológica, biomecánica u otra pueda afectar al correcto desarrollo de la intervención y de sus consecuencias. Durante la intervención se deberá disponer de una gama adecuada de tamaños de implantes.

- **Peroperatorio :** La correcta selección del tipo y tamaño de los implantes adaptados al paciente, así como su posición, son sumamente importantes.

- **Postoperatorio :** Los pacientes deben ser informados de las precauciones que deben tomar en su vida diaria para garantizar la duración de vida máxima de los implantes. Se aconseja efectuar un control postoperatorio regular que permita poner en evidencia signos precoces de quiebra del material. Los implantes pueden ser retirados después de la consolidación ósea. El deterioro del dispositivo después de la consolidación ósea no puede ser considerado como un disfuncionamiento o una alteración de las características del material. Se deberá establecer y aplicar un programa de reeducación adaptado.

6 | MANIPULACIÓN, ALMACENAMIENTO

La manipulación del material Erisma–LP debe efectuarse lo más raramente que posible y con precauciones. El almacenamiento de los implantes Erisma–LP (en su envase original) tiene que ser realizado con cuidado en un ambiente limpio y seco. No exponer los implantes Erisma–LP a radiaciones o temperaturas extremas. El incumplimiento de esas condiciones puede provocar una disminución de las características mecánicas que pueden conducir en algunos casos, a su ruptura. Los instrumentos quirúrgicos específicos de la instrumentación Erisma–LP tendrán que ser comprobados al nivel funcional antes de toda intervención.

7 | LIMPIEZA / DESCONTAMINACIÓN / ESTERILISACION

Las operaciones de limpieza, de descontaminación y de esterilización son imperativas por los implantes y los instrumentes antes y después el uso. Los implantes y los instrumentes deben extraerse de su embalaje de origen para las operaciones de limpieza, descontaminación y esterilización. Las operaciones de limpieza, de descontaminación y de esterilización deben respectar las recomendaciones en uso. Los implantes deben esterilizarse antes del empleo. Se recomienda esterilizar los implantes en un autoclave a vapor según el método empleado en los hospitales y las clínicas (valores recomendados abajo).

Método de esterilización	Autoclave
Ciclo	Prión
Temperatura	134°C
Duración de exposición	18 Min (Mínimo)

Sin embargo aconsejamos a los usuarios que no siguen el método recomendado validar su método recurriendo a técnicas de laboratorio adaptadas.

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